

Minutes of Meeting
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

August 10, 2016

Members Present: Ms. Janet Allen, Dr. Lee Carter (Vice-chair), Dr. Frances Cohenour (Chair), Dr. Elizabeth Dawson, Dr. Elizabeth Jacobson, Dr. Kelli Littlejohn Newman, Dr. Melinda Rowe, and Dr. Robert Smith

Members Absent: Dr. Pilar Murphy

Health Home/Probationary RCO Pharmacists Present via Teleconference: Allana Alexander, Lisa Channell, Amy Donaldson, Tammy Dubuc, Lydia Rather, Kristian Testerman, and Lauren Ward

Presenters Present via teleconference: Dr. Rachel Bacon

1. OPENING REMARKS

Vice Chairperson Carter called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:47 a.m.

2. APPROVAL OF MINUTES

Vice Chairperson Carter asked if there were any corrections to the minutes from the May 11, 2016, P&T Committee Meeting.

There were no objections. Dr. Dawson made a motion to approve the minutes as presented and Ms. Allen seconded to approve the minutes. The minutes were unanimously approved.

3. PHARMACY PROGRAM UPDATE

Dr. Littlejohn Newman oriented the Committee members to the Provider Alerts that are available on the Agency's website and provided the following updates:

- Governor Bentley announced a Special Session with topics to be discussed including the addition of a state lottery and Medicaid funding.
- The P&T Update went into effect July 1. The Biological Injectables are now included in the PDL under the AHFS classification of disease-modifying antirheumatic agents.
- The Agency continues to work towards RCO implementation.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations was explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were a total of two manufacturer verbal presentations at the meeting.

5. PHARMACOTHERAPY CLASS RE-REVIEWS (Please refer to the website for full text reviews.)

The pharmacotherapy class reviews began at approximately 9:53 a.m. There were a total of 11 drug class re-reviews. The Skin and Mucous Membrane Antibacterials, Skin and Mucous Membrane Antivirals, Skin and Mucous Membrane Antifungals, Skin and Mucous Membrane Scabicides and Pediculicides, Skin and Mucous Membrane Local Anti-infectives, Miscellaneous, Skin and Mucous Membrane Anti-inflammatory Agents, Skin and Mucous Membrane Antipruritics and Local Anesthetics, Skin and Mucous Membrane Astringents, Skin and Mucous Membrane Keratolytic Agents, Skin and Mucous Membrane Keratoplastic Agents, Skin and Mucous Membrane Agents, Miscellaneous were last reviewed in February 2014. There were two new drug reviews: Daklinza[®] and Zeptatier[®].

Skin and Mucous Membrane Antibacterials: American Hospital Formulary Service (AHFS) 840404 Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane antibacterials included in this review are listed in Table 1 on page 6. Most of the agents within this class are available in a generic formulation. The antibacterial agents are approved for the treatment of various skin infections and bacterial vaginosis. Nuvessa[®] is a new 1.3% strength of metronidazole vaginal gel, which allows for single-dose treatment of bacterial vaginosis. In a trial of 255 women (outlined on page 28), the difference in therapeutic cure rates in patients taking metronidazole vaginal gel 1.3% once daily for 1, 3, or 5 days was not statistically different from patients taking metronidazole vaginal gel 0.75% once daily for 5 days.

There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane antibacterial is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane antibacterials within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane antibacterial is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Antivirals: AHFS 840406

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane antivirals included in this review are listed in Table 1 on page 47. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane antiviral is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane antivirals within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane antiviral is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Antifungals: AHFS 840408

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane antifungals included in this review are listed in Table 1 on page 70. Since the last review, three new agents have been FDA-approved: Efinaconazole (Jublia[®]), luliconazole (Luzu[®]), and tavaborole (Kerydin[®]). Efinaconazole and tavaborole are approved for the treatment of onychomycosis. Oral antifungals are more effective than topical agents for the treatment of onychomycosis. Topical monotherapy is recommended when the matrix area is not involved. Oral monotherapy or the combination of oral and topical therapy is recommended when at least 50% of the distal nail plate is involved, when the nail matrix area is involved, or if mycological criteria are known. Ciclopirox 8% solution, efinaconazole 10% solution, and tavaborole 5% solution have been shown to improve clinical and mycological cure rates compared to placebo in clinical trials. For the treatment of dermatophyte infections, studies have demonstrated similar efficacy among the various topical antifungals. Luliconazole, which is approved for the treatment of tinea pedis, tinea cruris, and tinea corporis, demonstrated higher rates of complete clearance of tinea infections compared to placebo, with a similar incidence of adverse events, in

two clinical trials. A recent mixed-treatment comparison meta-analysis of randomized controlled trials that included patients with dermatophytosis (excluding onychomycosis and tinea capitis) found no significant difference among the antifungals with respect to mycologic cure at the end of treatment.

Miconazole is newly available in a buccal tablet for the local treatment of oropharyngeal candidiasis, under the brand name Oravig[®]. The Infectious Diseases Society of America guidelines recommend the use of clotrimazole troches or miconazole buccal tablets as initial therapy for patients with mild oropharyngeal candidiasis and oral nystatin as an alternative treatment. Oral fluconazole is recommended for patients with moderate to severe disease.

There is insufficient evidence to support that one brand skin and mucous membrane antifungal is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane antifungals within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane antifungal is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Scabicides and Pediculicides: AHFS 840412

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane scabicides and pediculicides included in this review are listed in Table 1 on page 155. These agents are approved to treat pediculosis and scabies. When treating scabies and lice, the goal of therapy is to eradicate the parasite. All of the products are available in a generic formulation, with the exception of benzyl alcohol, crotamiton, and ivermectin.

Previously, permethrin was recommended as first-line therapy and lindane as second-line in the guidelines by the Centers for Disease Control (CDC) and the American Academy of Pediatrics. Lindane is no longer recommended by the American Academy of Pediatrics. The CDC guidelines include lindane as an option when other treatments have failed. Incorrect use of lindane can be neurotoxic; its use should be restricted to patients for whom prior treatments have failed or who cannot tolerate safer medications. Lindane should not be used to treat premature infants, persons with human immunodeficiency virus, a seizure disorder, women who are pregnant or breast-feeding, persons who have very irritated skin or sores where the lindane will be applied, infants, children, the elderly, and persons who weigh less than 110 lbs. Retreatment with lindane should be avoided.

None of the pediculicides are 100% ovicidal and resistance has been reported with lindane, pyrethrins, and permethrin. Overall, the comparative success rates of topical pediculicides have been shown to be

approximately 57 to 99% with permethrin, 45 to 95% with piperonyl butoxide and pyrethrins, 60 to 88% with lindane, and 78% with malathion. The newer agents, which include benzyl alcohol, ivermectin, and spinosad, have shown cure rates of 75%, 71 to 75% and 93 to 94%, respectively, although there is limited published literature confirming these results. Permethrin is recommended as first-line therapy for the treatment of scabies in the guidelines by the CDC. Crotamiton also has a role as an antipruritic for those with scabies. All patients treated for scabies should expect the rash and itching to continue for approximately two weeks after treatment. The CDC recommends permethrin for pediculosis pubis.

Therefore, all brand skin and mucous membrane scabicides and pediculicides within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Lindane possesses an extensive adverse effect profile compared to the other brands and generics in the class (if applicable).

No brand skin and mucous membrane scabicide or pediculicide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Lindane should not be placed in preferred status regardless of cost.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Local Anti-infectives, Miscellaneous: AHFS 840492

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane miscellaneous local anti-infectives included in this review are listed in Table 1 on page 187. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane miscellaneous local anti-infective is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane miscellaneous local anti-infectives within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane miscellaneous local anti-infective is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Local Anti-inflammatory Agents: AHFS 840600

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane anti-inflammatory agents included in this review are listed in Table 1 on pages 213 and 214. The skin and mucous membrane anti-inflammatory agents are approved for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. There is at least one topical corticosteroid available in a generic formulation in each potency category and hydrocortisone is available over the counter. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane anti-inflammatory agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane anti-inflammatory agents within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane anti-inflammatory agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Antipruritics and Local Anesthetics: AHFS 840800

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane antipruritics and local anesthetics included in this review are listed in Table 1 on page 293. Several of the products are available in a generic formulation. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane antipruritic or local anesthetic is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane antipruritics and local anesthetics within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane antipruritic or local anesthetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Astringents: AHFS 841200

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that aluminum chloride is the only skin and mucous membrane astringent that is currently available. It is approved for the treatment of hyperhidrosis. There have been no major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane astringent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane astringents within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane astringent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Keratolytic Agents: AHFS 842800

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the skin and mucous membrane keratolytic agents included in this review are listed in Table 1 on page 347. Salicylic acid is now available as an ointment, under the brand name Bensal HP®. It is approved for the treatment of inflammation and irritation associated with dermatitis, including eczematoid conditions and complications associated with pyodermas; treatment of insect bites, burns, and fungal infections. There have been no other major changes in the prescribing information, treatment guidelines, or clinical studies since this class was last reviewed.

There is insufficient evidence to support that one brand skin and mucous membrane keratolytic agent is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand skin and mucous membrane keratolytic agents within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand skin and mucous membrane keratolytic agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Keratoplastic Agents: AHFS 843200

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that currently there are no prescription medications classified by American Hospital Formulary Service (AHFS) as keratoplastic agents.

No brand skin and mucous membrane keratoplastic agent is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 843200 in the Preferred Drug List (PDL) screening process. If new prescription keratoplastic agents are added, it is recommended that this class be re-reviewed.

There were no further discussions on this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Skin and Mucous Membrane Agents, Miscellaneous: AHFS 849200

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the miscellaneous skin and mucous membrane agents included in this review are listed in Table 1 on pages 360 and 361. The miscellaneous skin and mucous membrane class includes a diverse group of products used to treat many skin conditions, including actinic keratoses, atopic dermatitis, basal cell carcinoma, cutaneous T-cell lymphoma, Kaposi's sarcoma, mucositis, pain associated with anal fissure, postherpetic neuralgia, psoriasis, warts, and wounds. Many products are available in a generic formulation.

Since the last review, a generic formulation has become available for diclofenac, fluorouracil, tacrolimus, and calcipotriene-betamethasone. Additionally, calcipotriene-betamethasone is now available in a foam formulation. Mechlorethamine (nitrogen mustard) gel has also been approved since the last review, and it is indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy. Mechlorethamine has been used in the injectable formulation for decades. National Comprehensive Cancer Network guidelines recommend superficial therapies, including topical treatment with fluorouracil or imiquimod, photodynamic therapy (PDT), and cryotherapy, as treatments that should be reserved for those patients where surgery or radiation is contraindicated or impractical. There were no other major changes in the prescribing information since the class was last reviewed.

Due to the wide variety of products, as well as the range of Food and Drug Administration-approved indications, direct comparisons are difficult. Several guidelines have been updated since this class was last reviewed, which are summarized in Table 2.

At this time, there is not a role for the miscellaneous skin and mucous membrane agents in general use. Because these agents have narrow indications with limited usage, they should be available for special needs/circumstances that require medical justification through the prior authorization process.

Therefore, all brand miscellaneous skin and mucous membrane agents within the class reviewed are comparable to each other and to the generics in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand miscellaneous skin and mucous membrane agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

6. NEW DRUG REVIEWS (Please refer to the website for full text reviews.)

Daklinza®

Manufacturer comments on behalf of these products:

Daklinza® - Bristol Myers Squibb

Dr. Bacon commented that Daklinza® (daclatasvir) is a once-daily NS5A inhibitor indicated for use with the NS5B polymerase inhibitor Sovaldi® (sofosbuvir) for 12 weeks in the treatment of patients with chronic hepatitis C virus (HCV) genotype 1 or 3 infection. It is the first Food and Drug Administration (FDA)-approved all-oral regimen for the HCV genotype 3 infection that does not require co-administration of interferon or ribavirin. It is also approved for treatment of HCV genotype 1 or 3 in certain cirrhotic and post-transplant patients in combination with sofosbuvir and ribavirin.

FDA-approval was based on the results of ALLY-3 study in which Daklinza® (daclatasvir) was given in combination with Sovaldi® (sofosbuvir) for 12 weeks to 152 treatment-naïve and treatment-experienced patients with chronic HCV genotype 3 infection. High SVR12 rates (94 to 97%) were observed in patients without cirrhosis, regardless of prior treatment history; however, response rates in cirrhotic patients were much lower (58 to 69%). Prescribing information includes a limitation of use statement to inform prescribers that SVR rates are reduced in HCV genotype 3 infected patients with cirrhosis.

The AASLD/IDSA guidelines recommend daclatasvir plus sofosbuvir combination for 12 weeks (no cirrhosis) or 24 weeks (cirrhosis) as an alternative to sofosbuvir plus peginterferon and ribavirin for 12 weeks in HCV genotype 3 infection. Daclatasvir plus sofosbuvir with or without ribavirin is also recommended in other populations, including HCV genotype 1 and 2 (including prior sofosbuvir or HCV protease inhibitor failure), decompensated cirrhosis, and post-liver transplant. Screening for the presence of

NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93 in patients with cirrhosis who are infected with HCV genotype 1a is recommended prior to the initiation of treatment.

At this time, there is insufficient data to conclude that daclatasvir is safer or more efficacious than other brand or generic products within its class and that it offers a significant clinical advantage over other alternatives in general use. The drugs in this AHFS class are used in a specific patient population. Because these agents have narrow indications with limited usage, and very specific criteria must be met prior to initiating therapy, these agents should be managed through the medical justification portion of the prior authorization process.

No brand daclatasvir product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There was a discussion regarding the prior authorization request volume for the HCV antiviral class. Dr. Littlejohn Newman stated that requests are received daily. Alabama Medicaid follows the FDA labeling for approval criteria and incorporates labeling changes as they occur. Dr. Rowe noted that reinfection can occur in hepatitis C patients, so requirements are in place to reduce this risk. The Agency works with hepatologists to set these standards. Dr. Littlejohn Newman commented that post-treatment SVR rates are followed whenever possible. This is an area in which the RCO pharmacists are engaged with prescribers. Additionally, any requests for HCV antivirals must meet clinical criteria for approval, including the preferred agents within the class. Vice Chairperson Carter asked the P&T Committee members to mark their ballots.

Zepatier[®]

Manufacturer comments on behalf of these products:

Zepatier[®] - Merck

Dr. Bacon commented that Zepatier[®] (elbasvir/grazoprevir) is a once-daily fixed-dose combination tablet containing the NS5A inhibitor elbasvir and the NS3/4A protease inhibitor grazoprevir that is indicated with or without ribavirin for treatment of chronic hepatitis C virus (HCV) genotypes 1 or 4 infection in adults. The approved regimen (with or without ribavirin) and treatment duration (12 or 16 weeks) vary based on HCV genotype, prior treatment history and, for patients HCV with genotype 1a infection, the presence of certain NS5A polymorphisms at baseline. Prior to initiating treatment with Zepatier[®], the prescribing information recommends testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance associated polymorphisms to determine dosage regimen and duration. Lower sustained virologic response (SVR12) rates were observed in HCV genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Zepatier[®] joins several other regimens currently recommended by the consensus guidelines for the treatment of HCV genotype 1 and 4 infection, most of which are all-oral.

The FDA-approval was based on the results of several clinical trials (including C-EDGE TN, C-EDGE COINFECTION, C-SURFER, C-SCAPE, C-EDGE TE, and C-SALVAGE) totaling over 1300 patients, including patients with chronic HCV genotype 1 or 4 infections with and without cirrhosis. Overall SVR rates following treatment with 12- and 16-week regimens (some of which included ribavirin) ranged from

94 to 97% in genotype 1-infected patients and from 97 to 100% in genotype 4-infected patients across trials for the approved treatment regimens. Due to reduced SVR rates, product labeling recommends screening genotype 1a-infected patients for certain NS5A genetic variations prior to starting treatment.

At this time, there is insufficient data to conclude that elbasvir/grazoprevir is safer or more efficacious than other brand or generic products within its class and that it offers a significant clinical advantage over other alternatives in general use. The drugs in this AHFS class are used in a specific patient population. Because these agents have narrow indications with limited usage, and very specific criteria must be met prior to initiating therapy, these agents should be managed through the medical justification portion of the prior authorization process.

No brand elbasvir/grazoprevir product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on this agent. The P&T Committee members were asked to mark their ballots.

7. RESULTS OF VOTING ANNOUNCED

The results of voting for each of the therapeutic classes were announced; all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

8. NEW BUSINESS

The dates for the upcoming Alabama Medicaid P&T Meetings were provided and are as follows: November 9, 2016, February 8, 2017, and May 10, 2017.

Voting for the next Chair and Vice Chair will occur via email.

9. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for November 9, 2016 at the Medicaid Building in the Commissioner's Board Room.

10. ADJOURN

There being no further business, Dr. Carter moved to adjourn and Ms. Allen seconded. The meeting adjourned at 10:46 a.m.

Appendix

RESULTS OF THE BALLOTING
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee
August 10, 2016

A. **Recommendation:** No brand skin and mucous membrane antibacterial is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe MD Approve Approve as amended Disapprove No action

Medical Director

Patricia Veil Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action

Commissioner

B. Recommendation: No brand skin and mucous membrane antiviral is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

No brand monoamine oxidase inhibitor is recommended for preferred status, regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hall Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action

Commissioner

C. Recommendation: No brand skin and mucous membrane antifungal is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hall Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action

Commissioner

D. Recommendation: No brand skin and mucous membrane scabicide or pediculicide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rouss Approve Approve as amended Disapprove No action

Medical Director

Kathy Heel Approve Approve as amended Disapprove No action

Deputy Commissioner

Steph Approve Approve as amended Disapprove No action

Commissioner

E. Recommendation: No brand skin and mucous membrane miscellaneous local anti-infective is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rouss Approve Approve as amended Disapprove No action

Medical Director

Kathy Heel Approve Approve as amended Disapprove No action

Deputy Commissioner

Steph Approve Approve as amended Disapprove No action

Commissioner

F. Recommendation: No brand skin and mucous membrane anti-inflammatory agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Gabby Hull Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action
Commissioner

G. Recommendation: No brand skin and mucous membrane antipruritic or local anesthetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda S. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Gabby Hull Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action
Commissioner

H. Recommendation: No brand skin and mucous membrane astringent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hull Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action

Commissioner

I. Recommendation: No brand skin and mucous membrane keratolytic agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hull Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action

Commissioner

J. Recommendation: No brand skin and mucous membrane keratoplastic agent is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 843200 in the Preferred Drug List (PDL) screening process. If new prescription keratoplastic agents are added, it is recommended that this class be re-reviewed.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hull Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action

Commissioner

K. Recommendation: No brand miscellaneous skin and mucous membrane agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hull Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action

Commissioner

L. Recommendation: No brand daclatasvir product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hall Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action
Commissioner

M. Recommendation: No brand elbasvir/grazoprevir product is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

Melinda A. Rowe, MD Approve Approve as amended Disapprove No action

Medical Director

Kathy Hall Approve Approve as amended Disapprove No action

Deputy Commissioner

[Signature] Approve Approve as amended Disapprove No action
Commissioner

Respectfully submitted,

Rachel Bacon

August 16, 2016

Rachel Bacon, PharmD

Date